

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

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| Applicant's or agent's file reference 21496-1PC | FOR FURTHER ACTION | See item 4 below |
| International application No. PCT/US2004/001152 | International filing date (<i>day/month/year</i>) 15 January 2004 (15.01.2004) | Priority date (<i>day/month/year</i>) 15 January 2003 (15.01.2003)] |
| International Patent Classification (IPC) or national classification and IPC ⁷ A61B 1/00 | | |
| Applicant USGI MEDICAL CORP. | | |

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|-------------------------------------|---|---|-----------|---------------------|--------------------------|------------|----------|--------------------------|-------------|--|--------------------------|------------|----------------------------|-------------------------------------|-----------|---|--------------------------|------------|-------------------------|--------------------------|-------------|--|-------------------------------------|--------------|---|
| 1. | This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a). | | | | | | | | | | | | | | | | | | | | | | | | |
| 2. | This REPORT consists of a total of 7 sheets, including this cover sheet. In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead. | | | | | | | | | | | | | | | | | | | | | | | | |
| 3. | <p>This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 60%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> | <input checked="" type="checkbox"/> | Box No. I | Basis of the report | <input type="checkbox"/> | Box No. II | Priority | <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | <input type="checkbox"/> | Box No. IV | Lack of unity of invention | <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | <input type="checkbox"/> | Box No. VI | Certain documents cited | <input type="checkbox"/> | Box No. VII | Certain defects in the international application | <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. II | Priority | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VI | Certain documents cited | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application | | | | | | | | | | | | | | | | | | | | | | | |
| 4. | The International Bureau will communicate this report to designated Offices in accordance with Rules 44 <i>bis</i> .3(c) and 93 <i>bis</i> .1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44 <i>bis</i> .2). | | | | | | | | | | | | | | | | | | | | | | | | |

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|--|---|
| <p style="text-align: center;">The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 740 14 35</p> | <p>Date of issuance of this report 15 July 2005 (15.07.2005)</p> <p>Authorized officer Masashi Honda</p> <p>Telephone No. +41 22 338 70 10</p> |
|--|---|

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 02 MAY 2005

PCT

WIPO

PCT

To:
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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

29 APR 2005

FOR FURTHER ACTION

See paragraph 2 below

Applicant's or agent's file reference

21496-1PC

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US04/01152

15 January 2004 (15.01.2004)

15 January 2003 (15.01.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61B 1/00 and US Cl.: 600/104

Applicant

USGI MEDICAL CORP.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

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Julian W. Woo

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Form PCT/ISA/237 (cover sheet) (January 2004)

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/01152

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/01152

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|--|-----|
| Novelty (N) | Claims <u>36-39,62,85,88</u> | YES |
| | Claims <u>1-35,40-61,63-84,86,87,89-96</u> | NO |
| Inventive step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1-96</u> | NO |
| Industrial applicability (IA) | Claims <u>1-96</u> | YES |
| | Claims <u>NONE</u> | NO |

2. Citations and explanations:

Please See Continuation Sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/01152

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 88-91 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims are indefinite for the following reason(s): In each of these claims, "a tool" lacks antecedent basis.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/01152

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claims 1-5, 7-13, 16, 17, 19, 21, 22, 25-27, 33, 34, 43-48, 52-61, 63, 66-68, 72, 75, 79, 80, 87, 93, and 96 lack novelty under PCT Article 33(2) as being anticipated by Matsui et al. (6,352,503). Matsui et al. disclose, in figures 1-29 and 43-47, an endoluminal tool deployment system and a method for deploying one or more tools, where the system and method have a generally cylindrical, elongated main body (1 or 101) with arm guide lumens (36, 37) and at least one tool arm (2) having a laterally stabilized, steerable distal end (29), where the distal end of a tool arm is deflectable in a single plane, where the tool arm is lockable, where the distal end of the tool arm comprises a plurality of adjacent links with hinge structures (see fig. 4); where the tool arm is axially and rotationally translatable with the arm guide lumen, which terminates at a distal tip of the elongated main body, where the elongated main body has a viewing scope lumen (13 or 113), where elongated main body (101) has an independently lockable first section (111) and an independently lockable second section (112), where distal end of the elongated main body is steerable in retroflexion (see figures 43-47), where the tool arm comprise pull wires (31) or two supports of a deployment frame, where the tool arm comprises flexible tube of shape memory material (see also col. 6, lines 37-40), and where distal terminations of two arm guide lumens and the viewing scope lumen are arranged in a generally triangular pattern (see fig. 1 or 23).

Claims 1-10, 13-15, 18, 43, 49-51, 72-74, 76-78, and 93-95 lack novelty under PCT Article 33(2) as being anticipated by Hecke (5,448,989). Hecke discloses, in figures 1 and 2, an endoluminal tool deployment system and a method for deploying one or more tools, where the system and method have a generally cylindrical, elongated main body (4 or a flexible tube according to col 3, lines 37 and 38) with an arm guide lumen and at least one tool arm (4-if the flexible tube is considered the elongated main body, or 9-if element 4 is considered the elongated main body) having a laterally stabilized, steerable distal end, where the distal end of a tool arm is deflectable in a single plane, where the tool arm is lockable, where the distal end of the tool arm comprises a plurality of adjacent links (5, 6) with hinge structures (22, 23) and pivot pins (24); where the tool arm (9) is axially and rotationally translatable with the arm guide lumen (of 4), which terminates at a distal tip of the elongated main body, where the elongated main body is steerable, and where elongated main body (4) has an independently lockable first section (2) and an independently lockable second section (3).

Claims 19, 20, 23, 24, 28-32, 35, 40-42, 64, 69, 70, 81, and 90-92 lack novelty under PCT Article 33(2) as being anticipated by Fritsch (5,441,499). Fritsch discloses, in figures 2 and 3, an endoluminal tool deployment system having a generally cylindrical, elongated main body (43 or 11) with an arm guide lumen and at least one tool arm (11 or 37-if element 11 is considered the elongated main body) having a laterally stabilized, steerable distal end (at 12), a shaft (11), and a tool deployment lumen (of 11), where the distal end of a tool arm is deflectable in a single plane, where the tool arm is lockable, where the distal end of the tool arm comprises a plurality of adjacent links (16) with hinge structures and pivot pins; where the tool arm (11) has pullwires (17, 18), where the tool arm (37) is axially and rotationally translatable with the arm guide lumen (of 11), which terminates at a distal tip of the elongated main body, where the elongated main body is steerable, and where the tool arm has steering cuff (19') and an end effector (13).

Claims 81-84, 86, and 89 lack novelty under PCT Article 33(2) as being anticipated by Scholly (DE 3504824). Scholly discloses, in figures 1-9, a tool arm (6) with a shaft (7) having a proximal end and a distal end with a distal section of plurality of adjacent links (11) attached by hinge structures (12), and means for selectively deflecting the distal section of the arm (9), where the distal section includes hinge structures with male (16) and female bearing (hole at 14) surfaces and pins (15), where two steerable sections curve in

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

opposite directions, where the means for deflecting the distal section comprises at least one pullwire (8), and where the links form a predetermined curvature.

Claims 36-39 lack an inventive step under PCT Article 33(3) as being obvious over Fritzsich in view of Scholly. Fritzsich discloses the invention substantially as claimed, but does not disclose an elongated main body with independently lockable and steerable first and section sections, where the second section is deflectable in retroflexion, where the distal end of the main body is directed toward the proximal end. Scholly teaches, in figures 1 and 9, an elongated main body with independently lockable and steerable first and section sections, where the second section is deflectable in retroflexion, where the distal end of the main body is directed toward the proximal end. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Scholly, to modify the elongated main body of Fritzsich's device, so that it has independently lockable and steerable first and section sections, where the second section is deflectable in retroflexion, where the distal end of the main body is directed toward the proximal end. Such a modification would allow Fritzsich's device to access and treat tissue in locations that would be difficult to reach with a more rigid main body.

Claim 62 lacks an inventive step under PCT Article 33(3) as being obvious over Matsui et al. in view of Heckelee. Matsui et al. disclose the invention substantially as claimed, but do not disclose that the distal section of the elongate main body comprises a plurality of adjacent links. Heckelee teaches, in figure 1, a system having an elongate main body with a plurality of adjacent links at its distal section. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Heckelee, to modify that elongate main body of Matsui et al., so that the distal section comprises a plurality of adjacent links. Such a modification would allow the elongate main body to assume positively a predetermined curvature and rigidity, and allow the device of Matsui et al. to be manipulated like a rigid instrument.

Claim 85 lacks an inventive step under PCT Article 33(3) as being obvious over Scholly. Scholly discloses the tool arm substantially as claimed, but does not disclose a tip section curve with a radius greater than that of the base curve. Nevertheless, it would have been a matter of design choice to modify the number of links in the arm of Scholly's device, so that the tip section curve has a radius greater than that of the base curve. The choice would be dependent upon the locations of tissue that require access with Scholly's device. That is, the curvatures and their radii of the tool arm can be varied according to the physical confines of the surgical environment.

Claim 88 lacks an inventive step under PCT Article 33(3) as being obvious over Matsui et al. in view of Fritzsich. Matsui et al. disclose the invention substantially as claimed, but do not disclose at least one spring configured to straighten out the distal section of the elongated main body. Fritzsich teaches, in figure 2, a spring configured to straighten out the distal section of an elongated main body. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Fritzsich, to include a spring on the elongated main body of the device of Matsui et al. Such a spring would allow the distal section of elongated main body to be pivoted from a working position back to a reference position.

Claims 1-96 meet the criteria set out in PCT Article 33(4), and thus an endoluminal tool deployment system, a tool arm, and a method for tool deployment have industrial applicability because the subject matter claimed can be made or used in industry.

INTERNATIONAL SEARCH REPORT

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PCT/US04/01152

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 1/00

US CL : 600/104

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/104, 139, 141, 142, 149

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---------------|---|---|
| X --- Y | US 5,441,499 A (FRITZSCH) 15 August 1995 (15.08.1995), See figures 2 and 3. | 19,20,23,24,28- 32,35,40- 42,64,69,70,81,90-92 ----- 36-39,88 |
| X --- Y | US 5,448,989 A (HECKELE) 12 September 1995 (12.09.1995), See figures 1 and 2. | 1-10,13-15,18,43,49- 51,72-74,76-78,93-95 ----- 62 |
| X --- Y | US 6,352,503 B1 (MATSUI et al.) 05 March 2002 (05.03.2002), See figures 1-29 and 43-47. | 1-5,7- 13,16,17,19,21,22,25- 27,33,34,43-48,52- 61,63,66- 68,72,75,79,80,87,93, 96 ----- 62,88 |

☒ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

23 March 2005 (23.03.2005)

Date of mailing of the international search report

29 APR 2005

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/01152

C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|-----------------------|
| X | DE 3,504,824 A1 (SCHOLLY) 14 August 1986 (14.08.1986), See figures 1-9. | 81-84, 86, 89 |
| --- | | |
| Y | | 36-39, 85 |
| A | US 3,266,059 A (STELLE) 16 August 1966 (16.08.1966), See entire document. | 1-96 |
| A | US 3,583,393 A (TAKAHASHI) 08 June 1971 (08.06.1971), See entire document. | 1-96 |
| A | US 4,700,693 A (LIA et al.) 20 October 1987 (20.10.1987), See entire document. | 1-96 |

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US04/01152

Continuation of B. FIELDS SEARCHED Item 3:
EAST BRS
search terms: hinge, pin, link